

## **REMARKS**

Claims 1-34 are pending in this application, and claims 1-28 have been allowed. The examiner has made various formal objections to the application, and has rejected claims 29-34. As discussed below, Applicants respectfully submit that the application is now in condition for allowance.

### **The Formal Objections Have Been Obviated**

On page 2 of the Office Action, a new declaration or an application data sheet is requested because the declaration submitted "does not identify the mailing or post office address of each inventor." An unexecuted substitute declaration is enclosed herewith; the executed version will be submitted shortly.

Also on page 2 of the Office Action, the examiner notes that the specification does not contain a reference to the applications to which it claims priority. The specification has been amended to recite the application's priority information.

On page 3 of the Office Action, a request is made for an abstract of the disclosure. A copy of the abstract of the PCT application to which this application claims priority is submitted herewith. No new matter has been added.

### **The Rejections Under 35 U.S.C. §102(b) Should be Withdrawn**

On page 3-4 of the Office Action, claims 29-32 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 5,422,116 to Yen *et al.* ("Yen"), U.S. Patent No. 5,147,698 to Cole ("Cole"), or U.S. Patent No. 5,474,989 to Hashimoto *et al.* ("Hashimoto"). Applicants respectfully traverse this rejection for the following reasons.

As the Examiner is aware, a prior art reference must disclose all the elements of a claim in order to anticipate the invention recited by that claim. MPEP § 2131. There must be no difference between the claimed invention and the reference disclosure as viewed by one of ordinary skill in the art. *Scripps Clinic & Research Fdn. v. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Put another way, "[a] claim is anticipated and therefore invalid only when a single prior art reference discloses *each and every limitation of the claim*." *Glaxo Inc. v. Novapharm Ltd.*, 52 F.3d 1043, 1047, *cert. denied*, 116 S. Ct. 516 (1995) (citations omitted) (emphasis added).

This invention relates, in part, to modified forms of chitosan, which is a polymer obtained from the deacetylation of chitin. Specification, page 1, lines 28-29. In particular, claims 29-32 are directed to *modified* chitosan polymers produced by particular methods of the invention. In those methods, an enzyme is reacted “with at least one phenolic compound in the presence of a chitosan polymer or oligomer.” Claim 1, page 34, lines 3-6. Thus, the term “modified chitosan polymer” recited by the claims has a specific meaning:

The term 'modified' as used herein means that the chitosan has chemically reacted with one or more species in solution. Without being limited by any particular theory, it is believed that the enzyme converts the phenolic compound to a reactive quinone species, and the chitosan polymer or oligomer then reacts to covalently bond with the quinone or species derived from the quinone.

Specification, page 15, lines 5-7. None of the cited references disclose such a modified chitosan polymer.

For example, Yen discloses a liquid aqueous ophthalmic composition comprising chitosan. Yen, col. 1, lines 48-49. The chitosan used in the composition “is commercially available.” *Id.*, col. 2, line 53. Yen does not disclose or suggest the modified chitosan of this invention.

Cole also does not disclose modified chitosan. Instead, Cole discloses pressure-sensitive adhesive films that are made from a “hydrophilic polymerizable premix.” Cole, col. 4, lines 21-24. The premix reportedly can be made from a wide variety of thickening agents, one of which is chitosan. *Id.*, col. 5, line 14; example 22, col. 14, line 19. Cole does not, however, disclose or suggest the modified chitosan of this invention.

Hashimoto discloses “a drug composition containing one or more poorly water-soluble drugs and a low molecular weight chitosan.” Hashimoto, col. 2, lines 37-39. Hashimoto then describes the low molecular weight chitosan it uses. *Id.*, col. 2, lines 40-54. Hashimoto does not, however, disclose or suggest the modified chitosan of this invention.

In sum, none of the references cited in the Office Action disclose modified chitosan. The references merely describe certain commercially available forms of chitosan and their uses. For that reason, Applicants respectfully submit that the rejections of claims 29-32 be withdrawn.

On pages 4-5 of the Office Action, claims 33-34 are rejected as anticipated by Hashimoto, Cole, or Yen. Unlike claims 29-32, these are not product-by-process claims. However, claims 33-34 are still directed to *modified* chitosan polymers. Because none of the references disclose such polymers, Applicants respectfully request that the rejection of these claims also be withdrawn.


### CONCLUSION

All of claims 1-34 are believed to be allowable. Should the examiner disagree, Applicants respectfully request an interview to discuss any issues that may remain.

No fee is believed to be due for this submission. However, if any fees are necessary for the entry of this submission or to avoid abandonment of this application, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

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Enclosures